

REMARKS/ARGUMENTS

Claims 6, 7, 10-12, 38-41, 49-58, and 60-66 are active in the present application.

The claims have been amended for clarity. No new matter is believed to have been added by these amendments.

The lineage committed human cells are defined as being differentiated to at least a point where they are programmed to develop ONLY into a specific type of cell. In other words, the lineage committed human cells are not progenitor cells, stem cells, or other type of totipotent, pluripotent, or multipotent cell. Examples of the lineage committed human cells are provided in the claims and listed on page 7, lines 14-22.

The Office Action suggests that since a particular cell type can develop into different types of cells, it confuses the issue of the cell composition that is programmed to develop into only one type of cell. Applicants disagree. Generally, the standard for assessing whether a claim is definite is the claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made. See MPEP § 2173.02. For example, even if a T cell can develop into a CD4+ or a CD8+ cell, the T cell can still be programmed to develop into only one type of T-cell. Thus, the meaning and scope of the lineage committed human cell as defined in the present claims is clear and definite to one of ordinary skill in the art.

With respect to mixtures, Applicants note that the claimed method can culture, for example, simultaneously, two types of lineage committed human cells, each of which is programmed to develop into one type of cell.

Nonetheless, to expedite prosecution and to directly address the issues raised in the Office Action, monocyte, leukocyte, T cell, B-cell, and mixtures have been removed from the current claim set.

Accordingly, withdrawal of the rejection under 35 U.S.C. § 112, second paragraph is requested. Also, in light of the amendments submitted herein, Applicants request withdrawal of the rejections of Claims 6-7, 10-12, 38-41, and 49-69; and of Claim 69 under 35 U.S.C. § 112, first paragraph.

The rejection of Claims 10-12, 38-40 and 49 under 35 U.S.C. § 102(b) over Emerson et al (U.S. Patent No. 5,437,994) are traversed for the reasons submitted previously. In view of the above-noted discussion and the amendment submitted herein, it is clear that Emerson et al do not describe the claimed method.

Rather, Emerson et al describe culturing human bone marrow stromal cells by a method where a liquid culture medium is replaced or perfused at a specified rate (see col. 4, lines 39 through col. 5, line 9 and col. 7, lines 60-64). The human bone marrow stromal cells employed in Emerson are not lineage committed cells as defined in the present claims, i.e., "differentiated to at least a point where they are programmed to develop into ONLY a specific type of cell." Bone marrow stromal cells are known to be multipotent or cells that can develop into many different types of cells, i.e., progenitor or stem cells, which is supported by the general knowledge concerning bone marrow stromal cells (see Prockop DJ. Marrow stromal cells as stem cells for nonhematopoietic tissues. *Science* 1997 Apr 4;276(5309):71-4 of record). As

noted, *supra*, multipotent cells are excluded from the pending claims. Accordingly, Applicants request withdrawal of the rejection over Emerson et al.

For these same reasons, Applicants also request that the rejection of Claims 10-12 and 38-39 under 35 U.S.C. § 102(b) over Emerson et al (U.S. patent nos. 5,605,822 or 5,635,386 or 5,646,043 or 5,670,147 or 6,326,198) be withdrawn as well.

Caldwell et al similarly describe culturing bone marrow stromal cells to detect GM-CSF secretion (see page 350, column 1). As noted above in the discussion of Emerson et al, bone marrow stromal cells are NOT lineage committed human cells as in the present claims. Therefore, withdrawal of the rejection of Claims 10, 12 and 38-40 under 35 U.S.C. § 102(b) over Caldwell et al is also requested.

If the Examiner requires further clarification of any issue in this application he is invited to contact the Applicants' undersigned representative to resolve the matter expediently.

Applicants submit the present application is now ready for allowance. Early notification of such allowance is earnestly solicited.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,
MAIER & NEUSTADT, P.C.



Jean-Paul Lavalleye, Ph.D.
Registration No. 31,451

Customer Number

22850

Tel: (703) 413-3000
Fax: (703) 413 -2220

Daniel J. Pereira, Ph.D.
Registration No. 45,518